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IV. Public Record

EPA has established a public record for this testing decision (docket number OPTS-42022) which includes:

(1) Federal Register notice containing the designation of hexachlorocyclopentadiene to the Priority List.

(2) Communications (public).

(a) Non-confidential letters.

(b) Confidential letters (separately held).

(c) Contact reports of telephone conversations.

(d) Meeting summaries.

(3) Published and unpublished data.

This record which includes basis information considered by the Agency in developing this decision is available for inspection in the OTS reading room from 8:00 a.m. to 4:00 p.m. on working days in Rm. E-107, 401 M St., SW., Washington, D.C. 20460.

(Sec. 4, 90 Stat. 2003 (15 U.S.C. 2601))

Dated: December 20, 1982.

Anne M. Gorsuch,

Administrator.

[FR Doc. 82-35277 Filed 12-23-82; 4:34 pm]

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(OPTS-42017; TSH-FRI 2238-1)

Methyl Isobutyl Ketone and Methyl Ethyl Ketone; Response to the Interagency Testing Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In the Fourth Report of the Interagency Testing Committee (ITC), published in the Federal Register of June 1, 1979, (44 FR 31866) the ITC designated methyle isobutyl ketone (MIBK) and methyle ethyl ketone (MEK) for priority consideration for health effects testing. Following publication of the ITC report, additional testing data were made available to EPA, and the major U.S. manufacturers of MIBK and MEK presented to the EPA plans for testing further the health effects of these chemicals. The Agency has concluded that the existing data are sufficient to evaluate some of the effects recommended for testing by the ITC. In other cases, the EPA believes that testing recommended by the ITC is not warranted by the available data. Finally, EPA has tentatively decided to accept the industry proposal in lieu of rulemaking to fill the remaining data gaps of concern to the Agency. Consequently, the EPA is not, at this time, initiating rulemaking to require health effects testing of MIBK and MEK. This notice constitutes EPA's response to the ITC as required by section 4(e) of the Toxic Substances Control Act. Interested persons are invited to comment on EPA's Conclusions as to what testing is needed and on the adequacy of the industry program.

DATE: All comments must be submitted by February 14, 1983.

ADDRESS: Written comments should bear the document control number OPTS-42017 and should be submitted in triplicate to: Document Control Officer (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-409, 401 M St. SW., Washington, D.C., 20460.

The administrative record supporting this action is available for public inspection in Rm. E-107 at the above address from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Douglas G. Bannerman, Acting Director, Industry Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-511, 401 M St. SW., Washington, D.C., 20460, Toll Free: (800-424-9065), In Washington, D.C.: (554-1404), Outside the USA: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION:

I. Introduction

Section 4(a) of the Toxic Substances Control Act (TSCA) authorizes the EPA to promulgate regulations requiring testing of chemical substances and mixtures in order to develop data

relevant to determining the risks that such chemicals may present to health and the environment. Section 4(e) of TSCA [90 Stat. 2010; (15 U.S.C. 2601 et seq.)] established an Interagency Testing Committee (ITC) to recommend to the EPA a list of chemicals to be considered for the promulgation of testing rules under section 4(a) of the Act.

The ITC placed methyl isobutyl ketone (MIBK) and methyl ethyl ketone (MEK) on its priority testing list submitted to the Administrator in April, 1979 and published in the Federal Register of June 1, 1979 (44 FR 31866). This notice is EPA's response to the ITC's recommendation that testing be required for MIBK and MEK.

II. Methyl Isobutyl Ketone

A. Background

Methyl isobutyl ketone (MIBK) is a saturated aliphatic ketone whose molecular formula is $C_6H_{12}O$.

Annual production capacity is believed to be 231 million pounds (Ref. 1). MIBK's annual production for the past 10 years has ranged from 150–210 million pounds. Imports have amounted to about 6 million pounds (Ref. 2).

MIBK is used primarily in industrial operations. The Chemical Economic Handbook states that sixty-four percent of the MIBK produced is used as a solvent for industrial coatings, 16 percent is exported, 10 percent is used as a raw material for antioxidant manufacture, and the remaining 10 percent is consumed in a variety of uses such as lube oil dewaxing, rare metal refining, and as a component of agricultural insecticides and of adhesives (Ref. 3). Consumer products containing MIBK include adhesives, fixatives and solvents (Ref. 4).

Releases of MIBK to the atmosphere can occur through fugitive emissions and incomplete removal of vapors from reaction gases before they are vented. MIBK may be released to water during the discharge of spent scrubbing water. Other releases may occur as a result of accidental spillage or disposal of solid wastes or sludges that contain ketones (Ref. 2).

The known chemical properties of MIBK include moderate water solubility, moderate rate of volatilization from water, soil and the pure material, and moderate atmospheric oxidation and photolysis in the presence of oxidants. Thus, MIBK would be expected to partition into the atmosphere where it would be photochemically degraded. This would lead to a short half-life for MIBK in the environment and minimal exposure to the general population (Ref. 2). MIBK is readily biodegraded in normal wastewater treatment facilities and in seawater (Ref. 5).

Human exposure to MIBK has been estimated by the National Institute for Occupational Safety and Health (NIOSH) to range between 1.5 and 1.8 million workers (Ref. 6). The affected industries have indicated that only 10 percent of the people included in the NIOSH estimates (150,000–180,000) are actually exposed to MIBK (Ref. 7). However, EPA considers that even the lower industry estimates indicate a substantial exposure to MIBK. The Agency believes that there is consumer exposure to MIBK as a result of uses of products containing MIBK, but the number of persons and level of exposure cannot be determined.

The ITC recommended MIBK for health effects testing because of high exposure. Specific ITC recommendations and the rationale for testing included: mutagenicity testing because of lack of data; teratogenicity testing because of the indication of possible teratogenicity of the related aliphatic ketone, MEK; chronic effects testing because although subchronic toxicity is well-characterized, long-term toxic effects of MIBK have not been studied sufficiently to predict chronic effects; and performance of an epidemiology study because of lack of data on long-term toxic effects and on chronic effects on humans. The ITC did not recommend any environmental effects or fate studies because MIBK exhibits high vapor pressure and undergoes chemical and biological degradation in the environment and therefore, "does not appear to pose a hazard to terrestrial animals" (44 FR 31868, June 1, 1979).

B. Testing Proposed by Industry

The Chemical Manufacturers Association (CMA) Ketones Program Panel (the Panel) has submitted protocols (Ref. 8) for the following tests which they have agreed to perform: (1) Mutagenicity of MIBK; (2) inhalation teratology of MIBK; (3) 90-day subchronic toxicity of MIBK. EPA will examine the data from these tests and determine whether there is need for additional testing. The Panel is prepared to undertake any further testing on MIBK, including carcinogenicity studies, that industry and EPA scientists agree is scientifically justified on the basis of the initial test results.

1. *Mutagenicity testing.* The Panel has proposed to test MIBK using a battery of five mutagenicity tests.

These tests are listed below; they will be initiated following publication of EPA's final decision following review of comments on this notice.

(a) Ames test (*Salmonella* +/− Activation).

(b) Mouse Lymphoma (L5178Y TK +/−).

(c) BALB/3T3 Mouse embryo cell transformation.

(d) Cytogenetic Study (Mouse micronucleus).

(e) Unscheduled DNA synthesis.

2. Inhalation Teratology Testing.

The Panel will initiate teratology test in two species (rats and mice) for MIBK. At least three doses will be used along with a negative control. Dose levels will be established after the completion of the subchronic toxicity study. The doses will be designed to satisfy the criteria in the Organization for Economic Cooperation and Development Teratogenicity Guideline No. 414 (Ref. 9). A schedule for initiation, completion, and delivery of results will be provided to the Agency.

3. *90-day Subchronic testing.* While subchronic inhalation studies have been conducted with MIBK, the CMA Ketones Panel will sponsor another study because (1) the MacEwen study (Ref. 11) cited by the ITC was done under hyperbaric conditions, and exposures were 24 hours per day (not typical of workplace exposure), and (2) female animals have generally not been studied.

The Ketones Panel study is designed to measure parameters indicative of toxicity (such as changes in body weight, organ weight, blood cytology, clinical chemistry and urine analysis) as well as an extensive histopathology examination of major organs and tissues. This study will be performed on male and female rats and mice, using whole body inhalation exposure to MIBK vapor, six hours per day, five days per week for 13 weeks at doses of 50, 250, and 1000 ppm. The study is now on test at Bushy Run Research Center, sponsored by CMA, and results should be available in early 1983. A 9-day vapor inhalation range-finding study was completed in June, 1982.

At the conclusion of the 90-day study, the Panel will report these data to the Agency. EPA will evaluate these data and make recommendations on the need for further testing to the Panel.

C. Decision Not To Initiate Rulemaking

The Panel's proposed testing program will resolve unanswered questions on mutagenicity, teratogenicity and chronic health effects of MIBK. These are the health effects of concern designated for consideration by the ITC.